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REMARKSDISCUSSION OF CLAIMS

In the Office Action, claims 1-5, 8, and 11 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 5,330,507 to Schwartz.

In the Office Action, claims 16-19, 22-29, and 31-33 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Number 4,289,144 to Gilman.

In the Office Action, claims 20, 21, and 30 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gilman as applied to claims 16 and 27 above, and further in view of U.S. Patent Number 5,411,025 to Webster.

In the Office Action, claims 6, 7, 9, 10, and 12-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In response thereto, claims 1, 6, 7, 12, 14, 17, 19, and 28 have been amended. Accordingly, claims 1-33 are now pending. Following is a discussion of the patentability of each of the pending claims.

Preliminary Matter

Claims 17, 19, and 28 have been amended to correct typographical errors. In particular, in line 1, "whereing" has been replaced with --wherein--. It is respectfully requested that the amendment to claims be accepted.

Independent Claim 1

Claim 1 recites a method for controlling a patient's heart rate. The method comprises transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch, positioning an atrial electrode in the patient's atrium, detecting the patient's atrial rate, and delivering stimulation pulses to

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the vagal electrode when a fast atrial rate is detected. The stimulation pulses are delivered at a level that reduces the atrial rate to a normal operating range.

Schwartz discloses a method and apparatus for effecting vagal stimulation to prevent or interrupt tachyarrhythmias. Stimulation of the vagus nerves is provided by placing electrodes (74, 76) around the left and right vagus nerve bodies (see Figures 1 and 2). The electrodes are coupled to a pair of electrical leads (68, 78) at a distal end, and the leads are coupled to a nerve pulse generator (126).

Schwartz does not disclose or suggest transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch. In Schwartz, the electrodes are the cuff-type which are surgically implanted around the vagus nerve or the impalement-type which are implanted within the vagus nerve. Such placement of the electrodes typically requires very invasive surgery via the neck, which produces a high risk to nerve damage.

Gilman discloses an atrial/ventricular lead having an inner ventricular lead and an outer atrial lead. The distal end of the leads include an electrode having tines. The atrial lead has an atrial sidearm lead which is sigmoidal shaped.

Gilman does not disclose or suggest positioning a vagal electrode proximate to the patient's right vagus nerve. In Gilman, the sidearm lead is geometrically shaped to position itself within the atrial chamber, and the tines allow the atrial electrode to be passively fixed onto the trabeculae of the atrial appendage. In accordance with the configuration of the sidearm lead, it would be difficult to position and secure an electrode to function as a vagal electrode because tines are typically ineffective when securing to smooth walls of the heart such as regions which are proximate to the right vagus nerve and near the cardiac branch.

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Webster discloses an electrophysiological mapping device having an outer catheter, an inner catheter slidable within the outer catheter, and an electronic activation and recording device for electrically activating electrodes on the inner catheter and/or recording electric signals received by the electrodes. The inner catheter comprises a tubular shaft extending longitudinally through the outer catheter tube. A plurality of flexible arms are located at the distal end of the tubular shaft. Each arm carries a plurality of spaced apart electrodes. The arms flex outwardly to form a "basket" when extended out of the outer catheter.

Webster does not disclose or suggest positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch. In Webster, the mapping device is configured to map a chamber of the heart such as the right atrium, left atrium, right ventricle, and left ventricle. When the inner catheter is extended, the arms flex outwardly to contact the surface of an entire chamber of the heart. As such, the "basket" configuration is not configured to be positioned proximate to the patient's right vagus nerve near the patient's cardiac branch. The "basket" portion of the mapping device is too large to be positioned proximate to the patient's right vagus nerve such as within the azygos vein or superior vena cava as disclosed in the specification of the present application. Furthermore, the specification of the present application is directed to a relatively long term implantable lead for chronic use, whereas Webster is directed to a short term mapping device for diagnostic purposes.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2-5 and 7-11

Claims 2-5 and 7-11 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

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Independent Claim 12

In the Office Action, claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, claim 12 has been rewritten in independent form including all of the limitations of base claim 1. It is respectfully submitted that amended claim 12 is in condition for allowance.

Dependent Claim 13

Claim 13 depends from claim 12 and is similarly patentable. Accordingly, it is respectfully submitted that claim 13 is in condition for allowance.

Independent Claim 14

In the Office Action, claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In response, claim 14 has been rewritten in independent form including all of the limitations of base claim 1. It is respectfully submitted that amended claim 14 is in condition for allowance.

Dependent Claim 15

Claim 14 depends from claim 14 and is similarly patentable. Accordingly, it is respectfully submitted that claim 14 is in condition for allowance.

Independent Claim 16

Claim 16 recites an implantable stimulation for enhancing a patient's vagal tone. The implantable device comprises a transvenous lead body and an electrode portion. The transvenous lead body has an insulating sheath surrounding at least one conductor. The at least one conductor is coupled to at least one proximal connector.

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The electrode portion is coupled to the conductor, and the electrode portion is configured to be positioned within a patient's azygos vein and dimensioned to make contact with tissue proximate to the cardiac branch of the right vagus nerve.

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 16 is in condition for allowance. Furthermore, due to the configuration of the transvenous lead disclosed in Gilman, it is unlikely that the atrial electrode (38) can be positioned within the azygos vein.

Dependent Claims 17-26

Claims 17-26 depend from claim 16 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 27

Claim 27 recites an implantable single-pass stimulation lead for controlling a patient's atrial rate. The stimulation lead comprises a transvenous lead body, an atrial electrode, and an electrode portion. The transvenous lead body has an insulating sheath having first and second conductors. The first and second conductors are electrically isolated and coupled to first and second proximal terminals. The atrial electrode is coupled to the first conductor and is configured on the lead body so as to be capable of sensing atrial signals. The electrode portion is coupled to the second conductor and is configured to be positioned within a patient's superior vena cava and dimensioned to make contact with tissue proximate to the cardiac branch of the right vagus nerve.

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 27 is in condition for allowance.

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Dependent Claims 28-33

Claims 28-33 depend from claim 27 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

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Date

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